

PCT

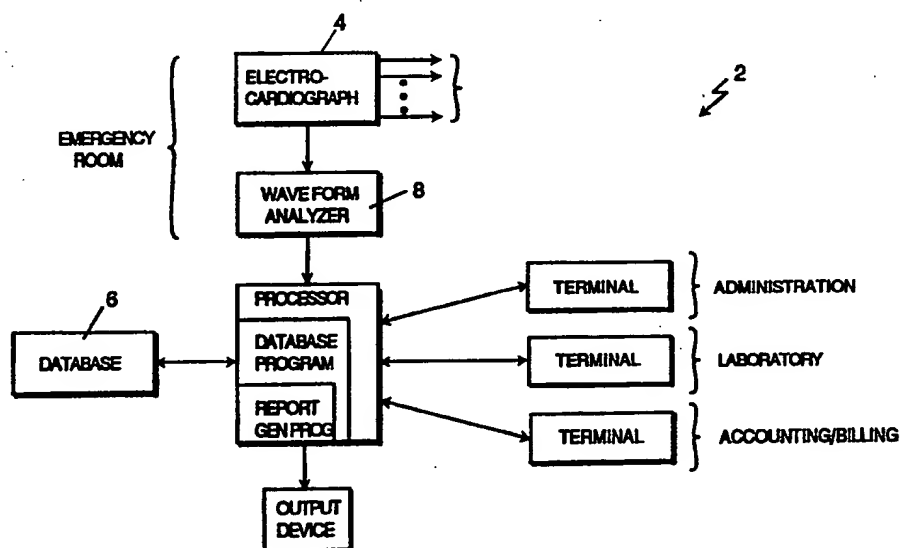
WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>5</sup> : <b>A61B 05/04</b>		<b>A1</b>	(11) International Publication Number: <b>WO 93/00047</b>
			(43) International Publication Date: <b>7 January 1993 (07.01.93)</b>
(21) International Application Number: <b>PCT/US92/05232</b> (22) International Filing Date: <b>19 June 1992 (19.06.92)</b> (30) Priority data: <b>721,157</b> <b>26 June 1991 (26.06.91)</b> <b>US</b> (71) Applicant: <b>NEW ENGLAND MEDICAL CENTER HOSPITALS, INC. [US/US]; 750 Washington Street, Boston, MA 02111 (US).</b> (72) Inventor: <b>SELKER, Harry, P. ; 26 Pine Tree Road, Wellesley, MA 02181 (US).</b> (74) Agent: <b>CLARK, Paul, T.; Fish &amp; Richardson, 225 Franklin Street, Boston, MA 02110-2804 (US).</b>		(81) Designated States: <b>CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, MC, NL, SE).</b>  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	

(54) Title: A CLINICAL INFORMATION REPORTING SYSTEM



(57) Abstract

A clinical information reporting system (2) for use with an electronic database (6) for a health care facility, the electronic database containing records for a group of patients and operational information which is accessed and used during the course of operation of the facility, the records containing clinical information for said group of patients, the reporting system (2) including an electrocardiograph (4) which generates ECG-related data for the group of patients; database application logic for incorporating the ECG-related data for the group of patients into the database (6); and report generating logic for generating a process of care report from the information stored in the database (6), the process of care report presenting selected process of care information derived from the database as a function of a clinically meaningful class of the group of patients, wherein the clinically meaningful class is defined at least in part in terms of the ECG-related data supplied by the electrocardiograph (4) and stored within the database (6).

BEST AVAILABLE COPY

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FI	Finland	MI	Mali
AU	Australia	FR	France	MN	Mongolia
BB	Barbados	GA	Gabon	MR	Mauritania
BE	Belgium	GB	United Kingdom	MW	Malawi
BF	Burkina Faso	GN	Guinea	NL	Netherlands
BG	Bulgaria	GR	Greece	NO	Norway
BJ	Benin	HU	Hungary	PL	Poland
BR	Brazil	IE	Ireland	RO	Romania
CA	Canada	IT	Italy	RU	Russian Federation
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LJ	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TC	Togo
DE	Germany	MC	Monaco	US	United States of America
DK	Denmark	MG	Madagascar		
ES	Spain				

- 1 -

A CLINICAL INFORMATION REPORTING SYSTEMBackground of the Invention

The invention relates to clinical information reporting systems.

5        Each year, over 500,000 Americans die of acute myocardial infarction (AMI, known as "heart attack"), including over 200,000 in hospitals. Were the medical advances of the last two decades consistently used, the mortality rate for hospitalized AMI patients would be  
10 much less. Medical care in this country's 6,000 hospitals varies, and current national AMI mortality rates are about twice those reported from major research centers. The problem is that physicians and hospitals do not consistently deliver optimal cardiac care.

15        Two fundamental problems underlie the failure to translate medical advances into results in this country's hospitals: 1) delays and errors in emergency room (ER) physician decision-making about the immediate care of the AMI patient, and 2) the lack of any credible and  
20 practical way to monitor and evaluate hospital AMI care results.

      The key advances in AMI care relate to the very first hours of care: new medications and procedures for immediate use, and admission to the coronary care unit  
25 (CCU). Even short delays in treatment can cost lives in the first few hours, as can mistakes in CCU admission, but both are currently common. Delays occur as ER physicians try to sort out and treat AMI patients from among the many others they must evaluate. For example,  
30 the typical ER delay in giving thrombolytic therapy is about two hours, despite its well-known loss of its life-saving effect if not given promptly. Admission decisions to the CCU are also often suboptimal. Of the early 1.5 million patients admitted to CCUs in this country each

- 2 -

year, fewer than half have true acute cardiac ischemia (the diagnosis including AMI as well as "unstable angina pectoris", which can quickly progress to an AMI), thus filling CCUs with unnecessary admissions. More costly in  
5 lives, each year approximately 20,000 AMI patients are inadvertently sent home from the ER without any care.

Once primarily the concern of physicians and researchers, because of the scale of the problem, the Federal government is now looking for ways to monitor,  
10 evaluate and improve the delivery of AMI care. Over the past two years, separate expert panels have been convened by the Health Care Financing Administration (HCFA), the Agency for Health Care Policy and Research (AHCPR), the National Institutes of Health (NIH), and the Institute of  
15 Medicine of the National Academy of Science, to find ways to improve the delivery of cardiac services. In each case, these panels and agencies have concluded that two major approaches are needed: 1) in order to improve the quality and speed of physicians' emergency care of AMI  
20 patients, methods are needed to assist physicians' emergency decision-making; and 2) in order to detect suboptimal care and to encourage continuous improvement, methods are needed to objectively assess the quality of physicians' and hospitals' AMI care.

25                   Summary of the Invention

In general, in one aspect, the invention features a clinical information reporting system for use with an electronic database in a health care facility. The electronic database contains records for a group of  
30 patients and it contains operational information which is accessed and used during the course of operation of the facility. The patient records include clinical information for the group of patients. The reporting system includes an electrocardiograph which generates

- 3 -

ECG-related data for the group of patients; database application logic for incorporating the ECG-related data for the group of patients into the database; and report generating logic for generating a process of care report from the information stored in the database. The process of care report presents selected process of care information derived from the database as a function of a clinically meaningful class of patients, wherein clinically meaningful class is defined at least in part in terms of the ECG-related data supplied by the electrocardiograph and stored within the database.

Preferred embodiments include the following features. Each of the patient records for a group of patients contains non-ECG related clinical information and the clinically meaningful class is defined in terms of the ECG-related data and non-ECG related clinical information stored within the database. The non-ECG related clinical information includes laboratory test results of blood enzyme analyses and the clinically meaningful class is defined in terms of the ECG-related data and the presence of an abnormal blood enzyme as indicated by the laboratory test results stored in the database. The abnormal blood enzyme is CPK. The database includes administrative information which is accessed and updated during the course of operation of the health care facility and the process of care information is derived at least in part from that administrative information. The database also includes patient billing information which is accessed and updated during the course of operation of the health care facility and the process of care information is derived at least in part from that patient billing information. The database contains triage decisions for the group of patients and the process of care report reports triage

- 4 -

decisions for the clinically meaningful class of the group of patients.

In general, in another aspect, the invention features a clinical information reporting system including an electrocardiograph which generates ECG-related data for the group of patients; a predictive instrument which receives from the electrocardiograph ECG data for each patient of the group of patients and which computes a probability for each patient therefrom, the computed probability being a probability that patient is experiencing a cardiac problem; database application logic for incorporating the ECG-related data for the group of patients and the computed probability for each patient into the database; and report generating logic for generating a process of care report from the information stored in the database, the process of care report presenting selected process of care information derived from the database as a function of the computed probabilities supplied by the predictive instrument.

The invention gives the health care facility the ability to access and view operational, clinical and process of care information within its electronic databases in terms of meaningful clinical classes for cardiac patients. The availability of both patient ECG data and other clinical information (e.g., laboratory enzyme analysis for patients) within the same database enables the user of the database to sort and present information in terms of clinical classes that are defined on the basis of both ECG data and non-ECG data. Since the patient information can now be accessed in terms of meaningful clinical classes defined at least in part by the ECG data, the user can generate process of care reports that would be very useful for risk management, quality assurance, utilization review and physician feedback purposes. Thus, the invention enables the

- 5 -

health care facility to much more effectively monitor and evaluate clinical care that is provided to cardiac patients.

Furthermore, such reports can be generated within the clinical setting and during the time frame in which they are needed (i.e., in real-time). The generation of such reports does not require the intervention of medical records clerks who must generate diagnostic codes for each patient based upon sometimes subjective and incomplete information supplied by the treating physician. Previously, if such reports had been desired, they could not be obtained in a timely manner but only through long, expensive research studies that required considerable manual effort and subjective or imprecise determinations of the diagnostic codes for the patients (i.e., the clinical class to which the patient belongs).

Also, in embodiments of the invention which incorporate a predictive instrument, the inclusion in the general database of the probability generated by the predictive instrument (e.g. the probability that acute ischemic heart disease is present) provides another useful and valuable variable for reporting and evaluating process of care information that can also be extracted from that database.

Other advantages and features will become apparent from the following description of the preferred embodiment and from the claims.

#### Description of the Preferred Embodiment

Fig. 1 is a block diagram of a clinical reporting system;

Fig. 2 presents the coefficients and variables of the logistic regression model used to compute the probability of acute cardiac ischemia;

- 6 -

Fig. 3 is an example of a process of care report which may be generated from the database using ECG data to identify the relevant patient population (i.e., AMI patients);

5 Fig. 4 is an example of another process of care report which may be generated from the database based upon predictive instrument generated ACI probabilities for the cardiac patients;

10 Fig. 5 is an example of a report of mean ACI probability by triage decision and by physician; and

Fig. 6 is an example of a report of mean ACI probability by triage decision and by resident training year.

#### Structure and Operation

15 Referring to Fig. 1, in a clinical information reporting system 2, ECG-related data generated by an electrocardiograph 4 is incorporated into a database 6 which also contains other clinical information about patients seen at a health care facility, as well as

20 operational information for the facility.

Electrocardiograph 4 produces a digitized ECG waveform for the patient being monitored. The ECG waveform is processed by a waveform analyzer 8 which identifies and quantifies its important characteristics and features.

25 Electrocardiograph 4 and waveform analyzer 8 may be part of a single instrument, for example, a Hewlett Packard Pagewriter XLi®, which is a 80386-based self-interpreting electrocardiograph. The Pagewriter generates an output referred to as a "BLOB" (Binary Large Object), which

30 contains the digitized waveform as well as a measurement matrix containing the results of the waveform analysis.

The output of waveform analyzer 8 passes to a predictive instrument 10 which evaluates the condition of the patient and generates a probability that the patient



- 7 -

is, for example, experiencing a particular type of cardiac condition. Predictive instrument 10 is designed in accordance with the design principles used for building other predictive devices such as the device for determining the probability of imminent death of the patient from cardiovascular disease such as is described in U.S. 4,957,115 to Dr. Harry P. Selker and the hand-held predictive instrument described by Michael W. Pozen et al. in "A Predictive Instrument to Improve Coronary-Care-Unit Admission Practices in Acute Ischemic Heart Disease" The New England Journal of Medicine, Vol 310 pp. 1273-1278, May 17, 1984, both of which are incorporated herein by reference.

In the described embodiment, predictive instrument 10 is a TIPI (time-insensitive predictive instrument) which uses a logistic regression-based equation for computing the probability that the patient is experiencing acute cardiac ischemia. The logistic regression equation is of the form:

$$P = 100 \times [1 - 1 / (1 + \exp(b_0 + \sum b_i x_i))],$$

where P is the probability of acute cardiac ischemia,  $b_0$  is a constant, and the  $b_i$ 's are coefficients of the variables  $x_i$  which are included in the model.

The variables which are used in this equation are shown in Fig. 2 along with the values of the coefficients and the values which the  $x_i$ 's can take for the different variables. Note that only the largest x is used per variable. Also ECG findings must be present in at least two leads, and S-T segment and T wave changes are "normal" if secondary to right or left complete bundle branch blocks, left ventricular hypertrophy, or a paced QRS. Only one type of abnormality is coded each for S-T segment and for T wave per patient (exclusive of TWISTDEP), use with elevation taking priority.

- 8 -

Deviations are expressed in mm using the standard ECG scale of 1mm = 0.1 mV.

The computer uses the inputs from electrocardiograph 4, waveform analyzer 8 to automatically compute the relevant probability using the above equation. The probability can be computed either in real time, while the patient is being evaluated, or it may be computed retrospectively.

The user performs the ECG in the usual way. At the time the ECG is being obtained, the user also enters patient identifying information and simple clinical data into the electrocardiograph. This includes, for example, patient date of birth, hospital ID #, age, sex, often a single diagnostic or symptomatic label (e.g. "chest pain", or "history of heart attack", etc.) medications, blood pressure, weight and perhaps other items which may be required by the computation that is to be performed by the predictive instrument.

The digitized ECG waveform, along with output from waveform analyzer 8, the computed probability from predictive instrument 10 and patient identifiers and other data which have been entered through electrocardiograph 4 by the physician are processed by a digital processor 12 which is running a database software program 14 such as, for example, the relational database program available from Sybase, Inc. and present in the Hewlett Packard ECG management system known as Tracemaster®. Database software program 14 opens the appropriate file and adds the information to patient records stored to database 6. If database 6 contains a record for the relevant patient, database program 14 adds the ECG-derived information to the existing record for that patient. If database 6 does not yet include a record for the patient, database program 14 creates a new

- 9 -

record for the patient, and stores the ECG-derived information in that new record.

Database 6 also contains non-ECG clinical information for patients including, for example, enzyme analysis, blood test results, urinalysis results, blood pressure readings, etc. which have been gathered during the evaluation and testing of the patients by the medical staff at the facility. Such non-ECG clinical information may be entered into database 6 in any of a number of different ways. For example, it may be automatically entered via a direct hook up with the laboratory assay machine which performs the test or it may be entered into database 6 through terminals 16 located elsewhere in the facility, such as, terminals found in the labs where the analysis is performed or terminals in the medical records department where medical records staff enter the handwritten notes generated by the medical staff who evaluate the patients

Database 6 also stores a broad range of other information which is generated and accessed in the course of the daily operation of the health care facility. In other words, the ECG-derived data is integrated into database 6 with a larger collection of data relating to the patients treated at the health care facility, the medical staff which provide the health care, the resources available for administering the care and information relating to the operational aspects of the health care facility. For example, it contains patient billing information generated by the accounting and billing departments, administrative and personnel information including information about the resident training program and the experience of the medical staff within the residency program, and other information which is necessary to running the facility.

- 10 -

Electrocardiograph 4 provides patient data which enables the user to classify cardiac patients in a clinically meaningful way. Meaningful clinical classes for cardiac patients may be defined in terms of

5 diagnostic criteria which often require both ECG patient data as well as other clinical data (non-ECG data) for the patient. For example, the diagnostic criteria for determining whether a patient has experienced a nonfatal myocardial infarction includes diagnostic ECG and

10 abnormal enzymes (e.g. creatine phosphokinase (CPK)). See, for example, Richard F. Gillum, M.D. et al., "International diagnostic criteria for acute myocardial infarction and acute stroke," American Heart Journal, p. 150, (July, 1984), incorporated herein by reference,

15 which presents diagnostic criteria for classifying cardiac patients. The stored ECG data available through the electrocardiograph is examined for the presence of the diagnostic ECG and laboratory results generated elsewhere in the cardiac care facility (and stored within

20 the same database) are examined for the presence of the abnormal enzymes, which along with characteristic ECG findings (e.g. Q waves of greater than 40 msec duration) confirm and/or define the diagnosis of acute infarction.

Similarly, accurate identification of the patients

25 who have experienced life-threatening hyperkalemic arrhythmic problems can be accomplished by examining patient ECG data along with other non-ECG data for the patient, namely, the patient's potassium level as determined by a test which is conducted by the

30 laboratory, i.e., another department of the health care facility. Identification of members of the relevant diagnostic class need not depend upon the crude and often inaccurate diagnostic codes which are generated by medical records personnel who often are relied upon to

35 enter patient medical information into a central

- 11 -

database. Thus, by combining the ECG data with the general patient information database for the facility, i.e., the database which includes other clinical information for patients, the user has immediate access  
5 to all data which is necessary for making meaningful classifications of patients.

For cardiac patients, meaningful clinical classes may also be defined in terms of the ECG patient data combined with another category of non-ECG data such as  
10 the probability generated by the predictive instrument. With the electrocardiograph-generated data and the output of the predictive instrument incorporated into the general database for the facility, it becomes possible to easily generate a broad range of meaningful reports on  
15 the performance of the facility in providing cardiac care, i.e., reports based upon valid and meaningful clinical classifications of patients. Moreover, the presence of the ECG data and the output of the predictive instrument in the larger database containing non-ECG data  
20 also makes it possible for the facility to generate those reports in real-time (i.e., while the patient is at the facility or within a short time after the report is requested by the user).

The electrocardiograph data within the database  
25 also enables the user to define an effective window into the data which is collected on patients that are diagnosed and/or treated by a health care facility. More specifically, it enables the user to produce reports about the process of care for cardiac patients which are  
30 based on meaningful clinical classes.

Moreover, since the electrocardiograph is a cardinal piece of equipment in the diagnosis and treatment of all patients passing through the facility that are suspected of having cardiac problems, it assures  
35 that the database is complete. That is, its use in the

- 12 -

clinical information reporting system to create a patient record within the general database (or to add ECG data to an already existing patient record) for every potential cardiac patient assures that the underlying database includes all patients who had cardiac problems. Thus, any report generated from that database about cardiac care will more accurately reflect the actual care being provided by the facility. Since all patients who received an electrocardiograph are automatically added to the database, the user may be reasonably confident that the report does not exclude cardiac patients who have been treated by the facility but through oversight or error were not added to the database. For example, under current practice patients erroneously not admitted to the hospital have no in-patient records or data, and errors cannot be found for that population. Also since the user can sort and report operational and process of care data based upon ECG based criteria, the user has greater confidence in the accuracy of the identification of cardiac problem types. This is particularly important for generating reliable and accurate risk management, quality assurance and utilization review reports for the health care facility.

The report generating features available through the database software may be used to generate such reports. Since the ECG-related patient data is present within the general database, the database software can be used to sort and/or present patient data based on ECG-based diagnostic class criteria.

The reports of particular importance and which have not previously been available to the administrator of the health care facility, the health care insurer, to malpractice litigation risk management personnel or to hospital resource utilization review functions are those which relate to the process of care provided by the

- 13 -

facility for clinical classes defined at least in part by ECG data. "Process of care" analysis is to be distinguished from "outcome" analysis, which looks at the results of the medical intervention, and from "structure" analysis, which looks at the physical makeup, condition and quality of the health care facility. In general, "process of care" concerns the type and quality of the actual medical care which is provided to patients. The following list suggests several examples of measures of process of care:

- Were patients with acute myocardial infarction admitted to the CCU?
- Were patients with hyperkalemic arrhythmias appropriately treated with agents to lower their potassium level?
- Do patients experiencing cardiac ischemia-related chest pain get nitroglycerine within five minutes of chest pain onset?
- Are patients with cardiogenic shock given a Swan-Ganz catheter and appropriate medications?
- Were patients triaged home from the ER of appropriately low likelihood (e.g. by the predictive instrument) of acute ischemia?
- Process of care information may be derived from operational data stored within the database. The operational data might include, for example:
  - credentials and training information on the physicians and other members of the medical staff;
  - billing information which indicates the types of services that were provided to patients;
  - administrative information indicating such things as the length of stay;
  - data from real-time hospital operations;
  - data from pharmacy records;

- 14 -

triage location data;  
billing information for the responsible MD;  
lab data;  
ICU nursing records; and  
5 orders for devices (e.g. Swan-Ganz catheters).

Examples of a variety of process of care reports that may be generated in real-time from the database are shown in Figs. 3-6.

Fig. 3 is a report of the total number of AMI  
10 patients who were sent to each triage location, i.e., CCU, ward or home, and the percentage of each group that died. The members of the relevant population (i.e., the members of the diagnostic class) are determined by ECG  
15 criteria (e.g. Q wave AMI) and CPK laboratory test results. The triage decision, i.e., where the AMI patient was sent is determined from billing and hospital information databases. Such a report is useful for  
20 quality assurance or risk management purposes in evaluating the correctness of the triage decisions that are being made.

Fig. 4 is a report of the mean probability of acute cardiac ischemia (ACI) as a function of where people were sent (i.e., as a function of the triage decision) and as a function of time period. The leftmost  
25 set of bars presents the mean probability for all patients seen in the emergency room (ER). The next three sets of bars present the mean probability for patients sent to each of the three triage locations. In each set of bars the left bar reports the mean probability for the  
30 cumulative quarter from September 1990 through December 1990 and the right bar reports the statistics for January 1991. In this case, the predictive instrument which is used operates as described in the previously mentioned Pozen et al. reference. That is, the predictive



- 15 -

instrument uses the ECG data for each patient to generate a probability that the patient was experiencing ACI.

The information reported in Fig. 4 is useful for risk management, utilization review, and quality assurance purposes, to name a few. For example, it helps assess who is being sent to the CCU and whether those patients really need CCU care. A low mean probability of ACI for the CCU patients would suggest that people are being sent to the CCU who might more appropriately be handled by the ward or who even would be sent home.

Fig. 5 is a report of the mean probability of ACI as a function of triage decision and as a function of the identity of the treating physician. The treating physicians are identified as Drs. A through E. Such a report is useful for determining another process of care concern, namely, is each of the doctors giving appropriate care. It could be used to identify those doctors, if any, who were improperly sending people with high ACI probabilities home and those doctors, if any, who were inappropriately using the limited CCU resources on patients with low ACI probabilities.

Fig. 6 is a report of the mean probability of ACI as a function of the triage decision and as a function of the residency training year of the treating resident physician. Such a report is useful for determining the effectiveness of the training of the resident physicians.

Other embodiments are within the following claims. For example, other monitoring devices (e.g. neonatal heart monitors) also play a correspondingly central role in diagnosing patient problems. Incorporating the output from such monitoring devices into the general operational database for the facility gives the user of the database a very valuable window through which to view all other patient related data in the database. That is, it enables the user to define meaningful clinical classes

- 16 -

based in part on such monitoring data and to then generate in real-time process of care reports for such clinical classes of patients.

What is claimed is:

- 17 -

Claims

1. A clinical information reporting system for use with an electronic database for a health care facility, said electronic database containing records for a group of patients and operational information which is accessed and used during the course of operation of the facility, said records containing clinical information for said group of patients, said reporting system comprising:
  - an electrocardiograph which generates ECG-related data for the group of patients;
  - database application logic for incorporating the ECG-related data for said group of patients into said database; and
  - report generating logic for generating a process of care report from the information stored in said database, said process of care report presenting selected process of care information derived from said database as a function of a clinically meaningful class of said group of patients, wherein said clinically meaningful class is defined at least in part in terms of the ECG-related data supplied by said electrocardiograph and stored within said database.
2. The clinical information reporting system of claim 1 wherein each of said patient records for a group of patients contains non-ECG related clinical information and wherein said clinically meaningful class is defined in terms of the ECG-related data supplied by said electrocardiograph and stored within said database and non-ECG related clinical information stored within said database.
3. The clinical information reporting system of claim 2 wherein said non-ECG related clinical information

- 18 -

includes laboratory test results of blood enzyme analyses and wherein said clinically meaningful class is defined in terms of the ECG-related data supplied by said electrocardiograph and stored within said database and  
5 the presence of an abnormal blood enzyme as indicated by said laboratory test results stored in said database.

4. The clinical information reporting system of claim 3 wherein said abnormal blood enzyme is CPK.

5. The clinical information reporting system of  
10 claim 1 wherein said database includes administrative information which is accessed and updated during the course of operation of the health care facility and wherein said process of care information is derived at least in part from said administrative information.

15 6. The clinical information reporting system of claim 1 wherein said database includes patient billing information which is accessed and updated during the course of operation of the health care facility and wherein said process of care information is derived at  
20 least in part from said patient billing information.

7. The clinical information reporting system of claim 1 wherein said database contains triage decisions for said group of patients and wherein said process of care report reports triage decisions for said clinically  
25 meaningful class of said group of patients.

8. A clinical information reporting system for use with an electronic database for a health care facility, said electronic database containing records for a group of patients and operational information which is  
30 accessed and used during the course of operation of the

- 19 -

facility, said records containing clinical information for said group of patients, said reporting system comprising:

an electrocardiograph which generates ECG-related  
5 data for the group of patients;

a predictive instrument which receives from said electrocardiograph ECG data for each patient of said group of patients and which computes a probability for each patient therefrom, said computed probability for  
10 each patient being a probability that patient is experiencing a cardiac problem;

database application logic for incorporating said ECG-related data for said group of patients and the computed probability for each patient into said database;  
15 and

report generating logic for generating a process of care report from the information stored in said database, said process of care report presenting selected process of care information derived from said database as  
20 a function of the computed probabilities supplied by said predictive instrument.

1/6

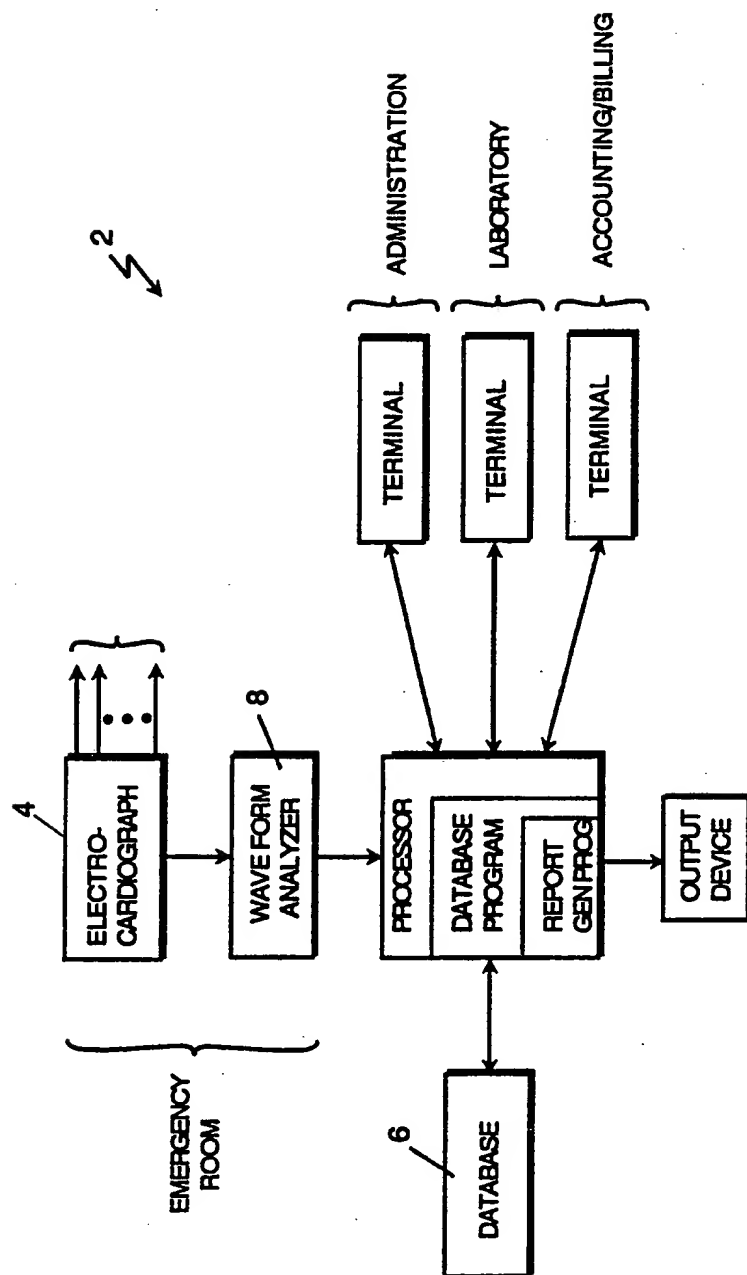


FIG. 1

SUBSTITUTE SHEET

2/6			
<u>Variable</u>	<u>Coefficient (b<sub>i</sub>)</u>		<u>Value (x<sub>i</sub>)*</u>
CONSTANT (b <sub>0</sub> )	-3.933		
CPAIN	1.231	Chest or left arm pain/pressure	1
		Not present	0
SX1CPAIN	0.882	Chest or left arm pain chief complaint	1
		Otherwise	0
MALESEX	0.712	Male	1
		Female	0
AGE	-1.441	Patient age 40 or less	1
		Otherwise	0
AGE50	0.667	Patient age greater than 50	1
		Otherwise	0
SEXAGE50	-0.426	Male patient age greater than 50	1
		Otherwise	0
QWAVE	0.616	ECG Q waves present	1
		Otherwise	0
STEL	0.314	ECG S-T segment elevated 2mm or more	2
		ECG S-T segment elevated 1-2mm	1
		Otherwise	0
STDEP	0.993	ECG S-T segment depressed 2mm or more	2
		ECG S-T segment depressed 1-2mm	1
		ECG S-T segment depressed 0.5-1mm	0.5
		Otherwise	0
TWEL	0.095	ECG T waves elevated ("hyperacute")	1
		Otherwise	0
TWINV	1.127	ECG T-waves inverted 5mm or more	2
		ECG T-waves inverted 1-5mm	1
		ECG T-waves flat	0.5
		Otherwise	0
TWISTDEP	-0.314	Both STDEP and TWINV not 0	1
		Otherwise	0

FIG. 2

SUBSTITUTE SHEET

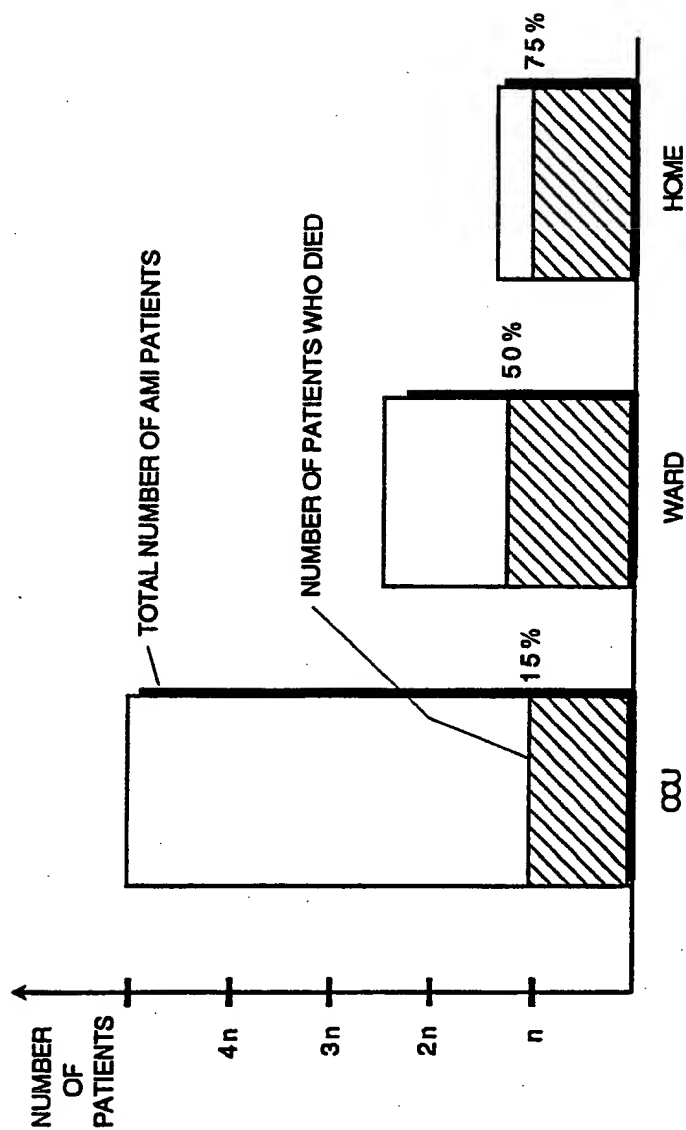
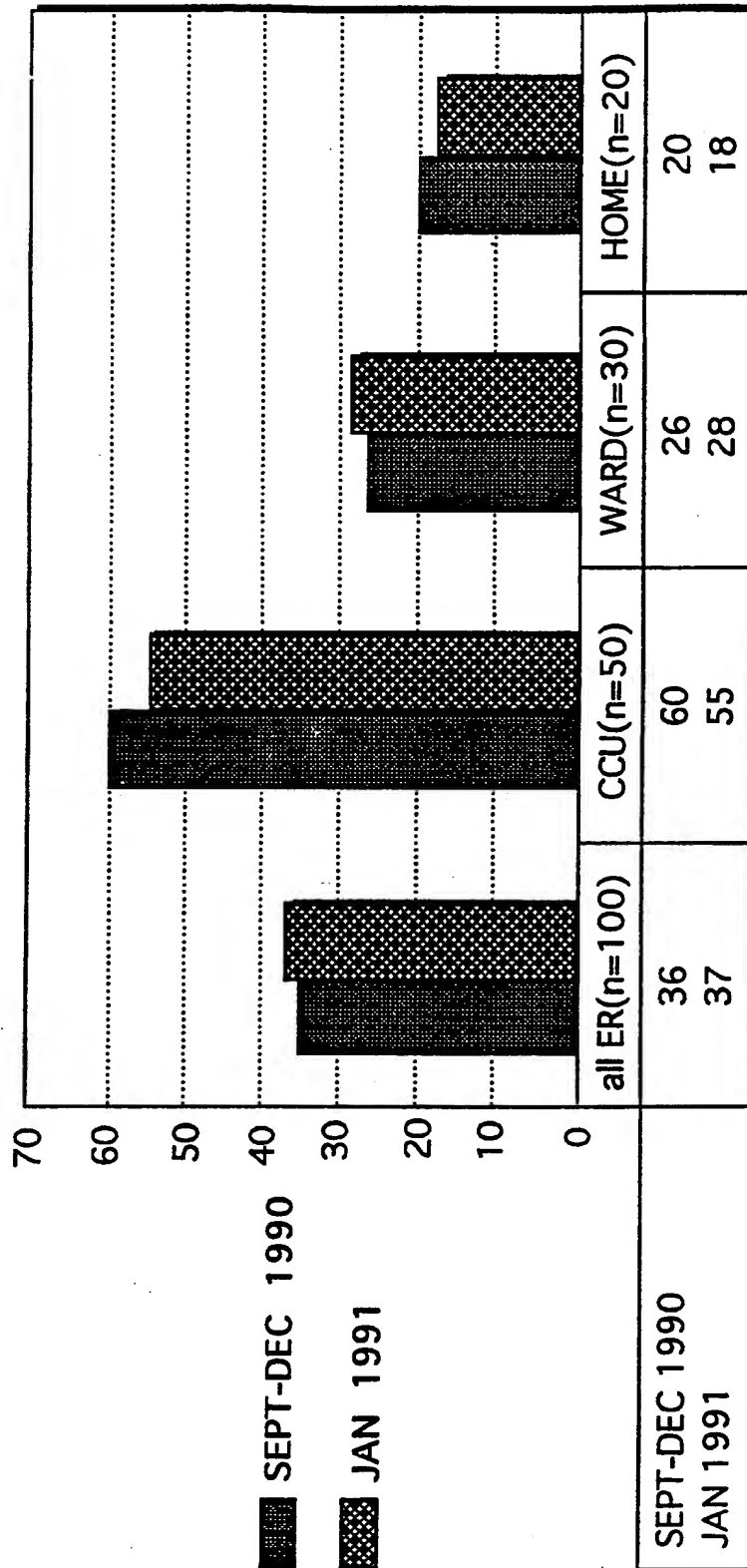


FIG. 3



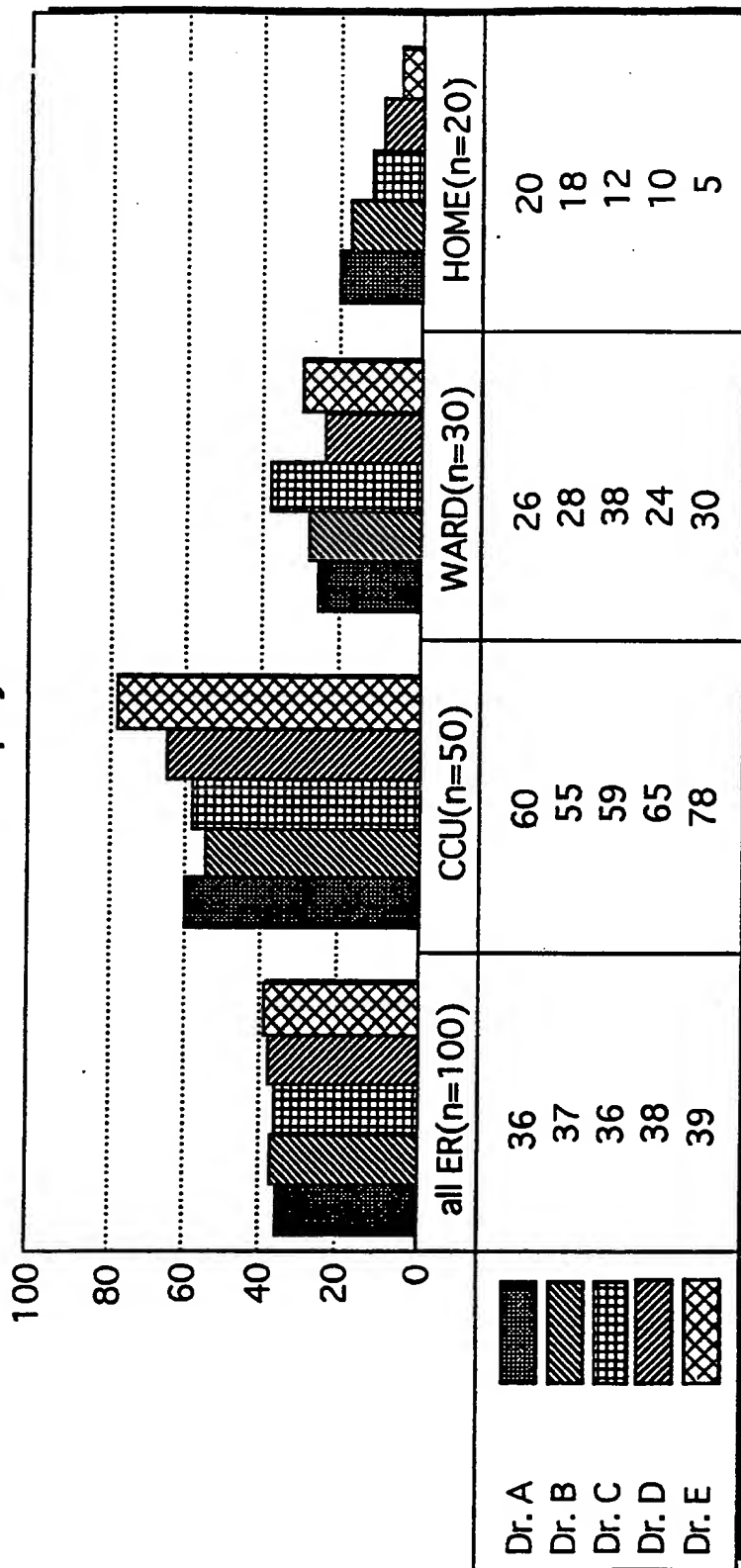
# Probability of Acute Cardiac Ischemia Mean ACI probability by triage decision Jan. v. Cumulative Quarter



% probability of ACI

FIG. 4

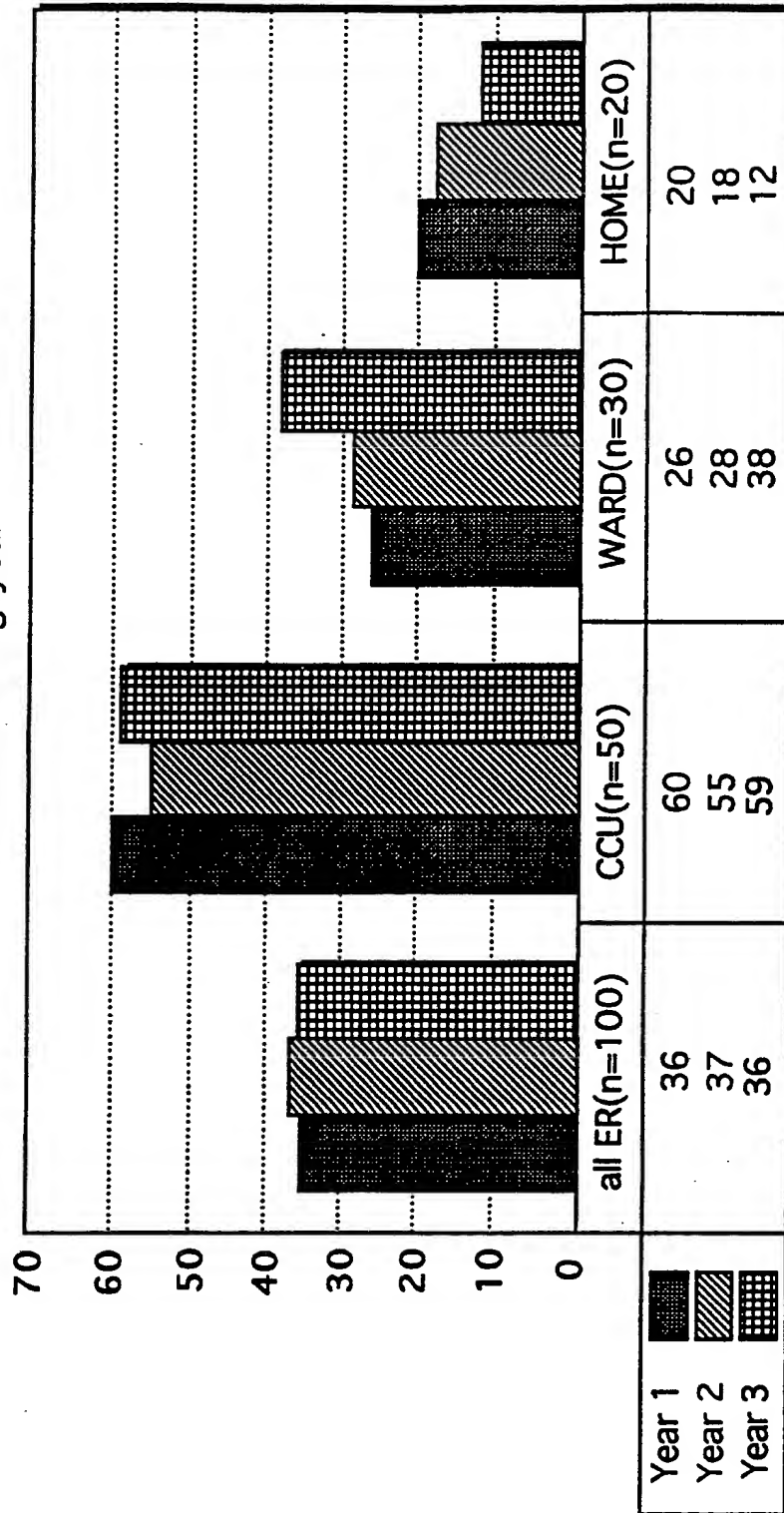
# Probability of Acute Cardiac Ischemia Mean ACI probability by triage decision and physician



% probability of ACI

FIG. 5

# Probability of Acute Cardiac Ischemia Mean ACI probability by triage decision and resident training year



% probability of ACI

FIG. 6

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US92/05232

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61B 05/04

US CL :128/696

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/695,364/413.06,128/702-705

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,679,144 (COX ET AL.) 07 July 1987, See entire document.	1-8
A P	US, A, 5,046,499 (BERGER) 10 September 1991, See entire document.	1-8
X	US, A, 4,998,535 (SELKER ET AL.) 12 March 1991, See entire document.	1-8
X P	US, A, 4,945,477 (EDWARDS) 31 July 1991, See entire document.	1-7
A	US, A, 4,957,115 (SELKER) 18 September 1990, See entire document.	1-8
A	US, A, 4,893,270 (BECK ET AL.) 09 January 1990, See entire document.	1-8
A	US, A, 4,610,254 (MORGAN ET AL.) 09 September 1986, See entire document.	1-8
A	US, A, 4,315,309 (COLI) 09 February 1982, See entire document.	1-8



Further documents are listed in the continuation of Box C.



See patent family annex

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principles or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Z"	document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

22 JULY 1992

Date of mailing of the international search report

~ NOV 1992

Name and mailing address of the ISA/  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Authorized officer

JEFFREY R. JASTRZAB

Facsimile No. NOT APPLICABLE

Telephone No. (703) 308-2097

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US92/05232

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	The New England Journal of Medicine, 17 May 1984, (M.W. POZEN), "A Predictive Instrument to Improve Coronary Care Unit Admission Practices in Acute Ischemic Heart Disease", Volume 310, pp. 1273-1278, entire document.	1-8
A	American Heart Journal, July 1984, (R.F. GILLUM, M.D. ET AL.) "International diagnostic criteria for acute myocardial infraction and acute stroke"; page 150, entire document.	1-8

**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: \_\_\_\_\_

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image  
problems checked, please do not report these problems to  
the IFW Image Problem Mailbox.**